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24
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,139	10/12/2000	John Jianhua Chen	S63.2-9178	7998

490 7590 04/09/2002

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

NOLAN, SANDRA M

ART UNIT	PAPER NUMBER
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1772

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DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.:

09/689,139

Applicant(s)

CHEN, JOHN JIANHUA

Examiner

Sandra M. Nolan

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement submitted on January 10, 2001 (Paper No. 2) was considered by the examiner.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-19, drawn to catheter balloons, classified in class 428, subclass 34.9.
 - II. Claims 20-30, drawn to methods of making catheter balloons, classified in class 264, subclass (unknown).
3. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product can be made by injection molding.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Ms. Lisa Lindquist on March 18, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

W/D. 6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "catheter balloon of claim 13" in line 1. There is insufficient antecedent basis for this limitation in claim 13.

Please correct the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

← 9. Claims 1-4, 8-13, 15-17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (US 5,348,538) in view of Fritz et al (US 5,735,830).

Wang teaches the production of balloon catheters (col. 1, lines 6-7) from polyethylenes (col. 2, lines 28-29).

Wang fails to teach the polymer/silane/peroxide system that applicant uses to make his balloon catheters.

Fritz teaches the production of medical instruments (title), such as catheters (col. 1, line 15), from compositions containing polyethylene (col. 3, line 66) that is grafted with silane (col. 4, line 22) and then crosslinked with water (col. 4, line 14) to produce Si-O-Si links in the final products (col. 4, lines 15-16). Peroxides are used (col. 5, lines 26+) along with polyethylene and silane in grafting (col. 4, lines 43+). Vinyltrimethoxysilane

Art Unit: 1772

is useful (col. 5, line 33-34). Fritz's products are transparent and can be steam sterilized (col. 2, lines 29-31).

The patents are analogous because both deal with the production of catheters from polyethylene-based formulations.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the compositions of Fritz to make the balloon catheters of Wang in order to make them transparent and steam sterilizable.

The motivation to employ the compositions of Fritz to make the balloon catheters of Wang is found at col. 2, lines 29-31 of Fritz, where the transparency and steam sterilizability of the Fritz products are disclosed. It is deemed desirable to make balloon catheters that are transparent and steam sterilizable so that the catheters do not obscure other objects in x-rays after they are inserted in to the body and so that they may be sterilized using conventional steam sterilizing devices.

- K 10. Claims 5-7, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Schmid (US 5,055,249).

Wang teaches the use of polyamides (col. 2, lines 32, 40, and 46) to make balloon catheters (title).

The examiner deems polyamides to be amine functional polymers because of the presence therein of amide linkages. Nylon (col. 2, line 40) is deemed to be a polyamide.

Wang fails to teach the amino functional polymer/silane combinations recited in these claims.

Art Unit: 1772

Schmid teaches that glycidyloxypropyltrimethoxysilane (col. 6, line 60) is among the silanes that react with the amino groups (col. 1, lines 53-55) in formulations containing polyamides (col. 1, line 42), to yield crosslinked polyamide articles (title). The crosslinked articles have improved mechanical and fire resistance properties (abstract).

The patents are analogous because both deal with articles made from polyamides.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the polyamide- and silane-containing formulations of Schmid in the production of the balloon catheters of Wang in order to give them improved mechanical and fire resistance properties.

The motivation to employ the polyamide- and silane-containing formulations of Schmid in the production of the balloon catheters of Wang is found in the abstract of Schmid, where the improved mechanical and fire resistance properties of Schmid's articles are discussed. It is deemed desirable to make balloon catheters that are mechanically strong and fire retardant in order to improve the useful life of the balloon catheters (because of their improved mechanical strength) and to facilitate their storage (because of their fire resistance).

Conclusion

Any inquiry concerning this communication should be directed to the Examiner, Sandra M. Nolan, whose telephone number is 703/308-9545. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the Examiner by telephone are unsuccessful, her supervisor, Harold Pyon, can be reached at 703/308-4251. The general fax number for the art unit is 703/305-5436. The fax number for after final communications is 703/872-9310. The receptionist answers 703/308-0661.



S. M. Nolan
Patent Examiner
Technology Center 1700

SMN/smn
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